

Remarks

Claims 1-10 and 13-19 are pending in this application. Claim 1 has been amended to amend an inadvertent error in terminology and to incorporate subject matter from claim 11. Claims 5 and 6 have been amended to incorporate subject matter from claim 11. Claims 11 and 12 have been canceled without prejudice. Claims 13 and 14 have been amended to change their dependencies and to make them grammatically compatible with claim 1. Claim 15 has been amended to correct punctuation. Claims 17-19 are new. Claim 17 contains subject matter of claims 1, 11, and 13. Claim 18 contains subject matter of claims 1, 11, and 14. Claim 19 contains subject matter of claims 1, 11, and 15. No new matter has been added to the application by virtue of these amendments.

The application now contains six independent claims and 17 total claims. Applicants previously paid for three independent claims. Therefore, there are now three independent claims in excess of three. The corresponding fee is enclosed herewith.

I. Response to Rejection under 35 U.S.C. § 112

Claims 1-4 and 8-16 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. More particularly, the recitation of "the hydrophobic heparinized polymer" in lines 13

and 15 of claim 1 were alleged to lack antecedent basis. Claim 1 has now been amended to correct the inadvertent reference to "the hydrophobic heparinized polymer" by replacing it with "the antithrombogenic heparinized polymer," for which there is antecedent basis at line 6.

Accordingly, withdrawal of the rejection is respectfully requested.

II. Response to Rejections under 35 U.S.C. § 103(a)

A. Legal Foundation for Examination under 35 U.S.C. § 103(a)

Before responding directly to the issues raised by the Office Action under Section 103, the legal foundation for sustaining such a rejection again will be reviewed. Briefly, an applicant for a patent is entitled to the patent unless the application fails to meet the requirements established by law. 35 U.S.C. §§ 101, 102, 103, 112. It is the USPTO's duty to issue a patent or establish that the applicant is not entitled to a patent under the law. *In re Warner*, 154 USPQ 173, 177 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Thus, the initial burden is on the USPTO to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). If no *prima facie* case of obviousness is established, then a rejection under Section 103 cannot properly be sustained. *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). If the USPTO establishes a *prima facie* case of

obviousness, then the burden of production shifts to the applicant to provide appropriate rebuttal, although the burden of persuasion always remains with the USPTO. *Id.* Such rebuttal may include arguments, amendments, and/or presentation of objective indicia of nonobviousness. However, such objective indicia are always relevant to a determination of nonobviousness whether or not a *prima facie* case of obviousness has been established. *Stratoflex Inc. v. Aeroquip Corp.*, 218 U.S.P.Q. 871, 879 (Fed. Cir. 1987). To establish a *prima facie* case of obviousness, the USPTO must show all of the limitations of the claimed invention in the prior art. *In re Ehrreich*, 200 U.S.P.Q. 504, 509-11 (C.C.P.A. 1979). The subject matter of the invention must be considered as a whole and through the eyes of a hypothetical person of ordinary skill, not expert skill, in the relevant art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983). References must also be considered as a whole, including subject matter that teaches away from the invention as well as subject matter that suggests the invention, and not for their isolated teachings. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 227 U.S.P.Q. 657, 669 (Fed. Cir. 1985). References may be combined if there would be a "reason to combine" them. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41, 1742 (2007). That is, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art" because "inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 1741. In nonobviousness analysis, one must "guard against slipping into the use of hindsight" and "resist the temptation to read into the prior art the teachings of the invention in issue." *Graham*, 383 U.S. at 36, 148 USPQ at 474; *KSR*, 127 S. Ct. at 1742. Finally, all the facts in evidence are evaluated, and patentability is determined on the totality of the record. *In re Corkill*, 226 USPQ 1005, 1008 (Fed. Cir. 1985). Factual determinations made by the USPTO must be based on a preponderance of the evidence, and legal conclusions must be correct. *In re Caveny*, 226 USPQ 1, 3 (Fed. Cir. 1985).

Pursuant to established legal authority, patentability under 35 U.S.C. § 103 requires a four-step factual analysis, which involves (1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claimed inventions, (3) resolving the level of ordinary skill in the pertinent art, and (4) utilizing the objective evidence of nonobviousness that may have been presented. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). After all of these factors have been considered, the ultimate legal conclusion on the issue of obviousness must be reached. With the

above background in mind the rejections under 35 U.S.C. § 103 will be discussed.

B. Factual and Legal Analysis

Claims 1-12 and 16 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,879,697 (Ding) in view of U.S. Patent No. 6,251,142 (Bernacca) and U.S. Patent No. 5,955,588 (Tsang).

Ding discloses drug-releasing coatings for medical devices. The abstract states:

[T]he coating comprises at least two layers: an outer layer containing at least one drug-ionic surfactant complex overlying a reservoir layer containing a polymer and the drug which is substantially free of an ionic surfactant. Upon exposure to the body tissue of a medical device covered with such coating, the ionically bound drug in the outer layer is released into body fluid or tissue. Following release of such bound drug, the ionic surfactant binding sites in the outer layer are left vacant. To maintain the pharmacological activity after delivery of the ionically bound drug, additional amounts of the drug are embedded or incorporated in the reservoir layer in a manner which allows the drug, which is substantially free of ionic surfactants, to complex with the vacant binding sites of the ionic surfactant of the outer layer.

See also, column 2, line 62, to column 3, line 16. Ding further states:

The complexes formed according to the present invention will result primarily from ionic interactions between negatively charged drugs and positively charged surfactants or positively charged drugs and negatively charged surfactants. However, certain secondary forces may also exist to contribute to the formation or maintenance of the complexes, such as hydrogen bonding, dipole-dipole interaction, charge-dipole interaction

Column 4, lines 8-15. Thus, Ding discloses non-covalent bonds between a charged drug and an oppositely charged surfactant. Ding also discloses mixtures of the drug and a polymer. Column 4, lines 24-37. The drug and polymer are not bonded to each other, because bonding of the drug to the polymer would prevent the drug from being released, which is a property of Ding's invention. Column 3, lines 13-17. Therefore, Ding fails to disclose covalent bonds between heparin and anything.

Bernacca discloses an implantation device in which at least a portion of the surface of the device is coated with a receptor capable of binding selectively with a ligand formed by combining an active principle (i.e., a drug or a diagnostic; col. 4, lines 60-63) with a substance capable of binding specifically to the receptor. Col. 3, lines 1-6. Preferred receptors are disclosed at col. 3, lines 18-20. Binding pairs are disclosed at col. 4, lines 18-22. Biotinylated heparin is disclosed as an example of a ligand. Col. 6, lines 45-49. Thus, Bernacca discloses what is presumably a covalently bonded ligand, i.e., heparin covalently bonded to biotin (a receptor-binding molecule), and Bernacca discloses releasable, non-covalent bonding between the ligand and a receptor.

Tsang discloses a non-thrombogenic coating for blood-contacting surfaces of medical devices. The coating consists of heparin covalently bonded to a hydrophobic silyl moiety. The

Office Action has interpreted the silyl moiety as disclosing a synthetic macromolecule bonded to a hydrophobic material.

Claims 1, 5, and 6 have been amended to define the macromolecule portion of the heparinized polymer as comprising a protein or a biopolymer. Claims 11 and 12 have been canceled without prejudice.

The combination of Ding, Bernacca, and Tsang fails to disclose each and every limitation of the relevant independent claims, and thus fails to render these claims unpatentable under Section 103. The dependent claims incorporate by reference the limitations of the base claims, and thus are free of the cited references, as well.

Therefore, withdrawal of the rejection of claims 1-10 and 16 over Ding, Bernacca, and Tsang is respectfully requested.

Claims 13-15 were not rejected over the cited art. New claims 17-19 incorporate subject matter of claims 13-15, respectively. Therefore, claims 17-19 are free of the art cited against claims 1-12 and 16. Allowance of these claims is, therefore, appropriate and requested.

III. Summary and Conclusion

Should the Examiner deem it advisable to conduct a telephone interview for any reason, the undersigned attorney would be most agreeable to receiving a telephone call to expedite the prosecution of the application.

For the reasons given above, Applicants respectfully request reconsideration and allowance of Claims 1-10 and 13-19 and passage of this application to issue.

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Respectfully submitted,



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